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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,643	03/23/2004	Aaron V. Kaplan	015471-000910US	3899

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EXAMINER

SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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08/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/807,643

Applicant(s)

KAPLAN ET AL.

Examiner

Ann Schillinger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,24 and 26-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,24 and 26-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/2/07, 5/31/07, 7/13/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claims 24-31, 33-45, 47-55, and 57-61 are objected to because of the following informalities: they are dependent claims that begin with an indefinite article, when definite articles should be used. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23, 24, 27-30, 32-37, 39, 41-43, 45-47, 49, 50, and 52-61 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Solovay (U.S. Pat. No. 6,482,227). For claim 32, Solovay discloses a radially expandable scaffold (30; col. 5, lines 28-29) having a first wall pattern (at 11, 30) and a second wall pattern (at 60, 43A, 43B); and circumferential anchors (80(a), 80(b), 40), which have an axial length at least 1.5 times the scaffold width prior to expansion, and they are capable of bending and extending to circumscribe the main vessel wall (see Figure 18). The Solovay reference is silent on the limitation of the anchors being able rotate relative to the prosthesis. However, Fearnot et al. (US Pat. No. 6,565,597) teaches rotating anchors in col. 3, line 12 through col. 4, line 35 for the purpose of creating a consistent, regular stent pattern that avoids entanglement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was

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made to use anchors that can rotate in order to create a consistent, regular stent pattern that avoids entanglement.

Solovay discloses the limitations of claim 24, 27, 28, and 45 as shown in Figure 15.

Solovay discloses the limitations of claim 29 in col. 7, line 67 through col. 8, line 1.

Solovay discloses the radiopaque marker of claim 30 in element 15.

Solovay discloses the limitations of claim 43 in col. 2, lines 61-66.

Solovay discloses the following of claim 46: a prosthesis for placement at an os opening from a main body lumen to a branch body lumen, the main body lumen having a main vessel wall with a portion of the main vessel wall opposing the os, said prosthesis comprising: a radially expansible scaffold (30; col. 5, lines 28-29) having at least a first wall pattern (11, 30); and at least one anchor (80(a), 80(b), 40) extending from an end of the scaffold, said anchor having a length sufficient to circumscribe the main vessel wall and reach the portion of the main vessel wall opposing the os when the scaffold is implanted in the branch lumen with said one end adjacent the os (see Figure 19), and wherein the anchors have an axial length which is at least 1.5 times the width of the scaffold prior to radial expansion (see Figure 18).

Solovay discloses the limitations of claim 47 as shown in Figure 19.

Solovay discloses the limitations of claims 49-51 as shown in Figures 15 and 19.

Solovay discloses the limitations of claims 52 and 53 in element 15 and col. 7, lines 6-7.

Solovay discloses the limitations of claims 54 and 55 in col. 2, lines 61-66.

Claims 56, 57, and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Hartley et al. (US Pub. No. 2003/0199967). Hartley et al. discloses the following of claim 56: a method

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for deploying a prosthesis across an Os opening from a main lumen to a branch lumen, the main body lumen having a main vessel wall with a portion of the main vessel wall opposing the os, said method comprising: positioning a first prosthesis (127) so that a scaffold lies within the branch lumen (109, 111, 113) and at least two anchors (121) extend into the main lumen (105); radially expanding the scaffold to implant said scaffold in the branch lumen (paragraph 0044); circumferentially deforming the anchors such that at least one of said anchors extends along the main vessel wall a sufficient distance to reach the portion of the main vessel wall opposing the os (see Figure 7).

Hartley et al. discloses the following of claim 57: a method of positioning a prosthesis across the ostium opening between a main vessel and a branch vessel, the main vessel extending in both an upstream direction and a downstream direction from the ostium, comprising the steps of: providing a radially expandable scaffold (115, 127, 129), having a first end and a second end and at least three anchors (121) extending from the first end (see Figure 7); and positioning the prosthesis such that the scaffold is within the branch vessel (127) and the anchors extend along the wall of the main vessel and all point in an upstream direction.

Hartley et al. discloses the limitations of claim 61 as shown in Figure 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 26, 44, 48, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay in view of Chobotov et al. (U.S. Pub. No. 2003/0125797). Solovay discloses the invention substantially as claimed, however, Solovay does not disclose the lengths of the anchors as being greater than at least 2 mm or 6mm. Chobotov et al. teaches the lengths of the anchors as being greater than at least 2 mm or 6 mm in paragraph 0125 for the purpose of enabling the prosthesis to treat a larger range of patients. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the lengths of the anchors greater than at least 2 mm or 6 mm in order to enable the prosthesis to treat a larger range of patients.

Solovay discloses the limitations of dependent claim 51 in Figures 15 and 19.

Claim 31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay or Hartley et al. in view of Fearnot et al. in view of Sheiban (U.S. Pat. No. 5,226,889). Solovay discloses the invention substantially as claimed, however, Solovay does not disclose placing a radiopaque marker on the balloon being used to expand the prosthesis. Sheiban teaches placing a radiopaque marker on the balloon being used to expand the prosthesis for the purpose of allowing the surgeon to view the position of the prosthesis with a fluoroscope. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place a radiopaque marker on the balloon being used to expand the prosthesis in order to allow the surgeon to view the position of the prosthesis with a fluoroscope.

Claims 32, 33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley et al. in view of Fearnot et al. Hartley discloses the method substantially as claimed, where the main body lumen having a main vessel wall with a portion of the main vessel wall

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opposing the os, said method comprising: positioning a first prosthesis (127) so that a scaffold lies within the branch lumen (109, 111, 113) and at least two anchors (121) extend into the main lumen (105); radially expanding the scaffold to implant said scaffold in the branch lumen (paragraph 0044); circumferentially deforming the anchors such that at least one of said anchors extends along the main vessel wall a sufficient distance to reach the portion of the main vessel wall opposing the os, and the anchors' length being 1.5 times the scaffold width (see Figure 7). However, Hartley et al. does not disclose that the anchors can rotate. Fearnot et al. teaches this in col. 3, line 12 through col. 4, line 35 for the purpose of creating a consistent, regular stent pattern that avoids entanglement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use anchors that can rotate in order to create a consistent, regular stent pattern that avoids entanglement.

Hartley et al. discloses claim 33 in Figure 7.

Hartley et al. discloses claim 35 in paragraph 0018.

Hartley et al. discloses claims 41 and 42 in elements 164, 166, and 168.

Claims 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley et al. in view of Fearnot et al. in further view of Imran et al. (U.S. Pat. No. 6,241,744). Solovay discloses the invention substantially as claimed, however, Solovay does not disclose using only one balloon to deploy on the anchors of the prosthesis. Imran et al. teaches using only one balloon to deploy on the anchors of the prosthesis for the purpose of decreasing implantation time. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use only one balloon to deploy on the anchors of the prosthesis in order to decrease implantation time.

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Claims 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley et al. in view of Sheiban (US Pat. No. 5,226,889). Hartley et al. discloses the invention substantially as claimed, however, Hartley et al. probably does not disclose mounting the prosthesis on a balloon catheter. Sheiban teaches using a balloon catheter in col. 2, line 54 through col. 3, line 49 for the purpose of assisting the inflations of the prosthesis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a balloon catheter in order to assist in inflating the prosthesis.

Response to Arguments

Applicant's arguments with respect to claims 23-61 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
August 3, 2007

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER